



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,298	02/25/2002	Kenneth Jacobs	GI 5358 CIP	7985
25291	7590	09/28/2004	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			HUNNICUTT, RACHEL KAPUST	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,298

Applicant(s)

JACOBS ET AL.

Examiner

Rachel K. Hunnicutt

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-14,16-20 and 34-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-20,43-59 and 62 is/are allowed.
- 6) ☒ Claim(s) 10,12,14,16,34-42,60 and 61 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0704.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Applicant's amendment filed July 12, 2004 is acknowledged. Claims 1-9, 11, 15, and 21-33 have been canceled. Claims 14, 34-38, 40, and 42 are amended. Claims 46-62 are new. Claims 10, 12-14, 16-20, and 34-62 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification regarding the required reference to priority documents is withdrawn in response to Applicant's amendment to the specification.

The objection to the specification regarding embedded hyperlinks is withdrawn in response to Applicant's amendment to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The rejection of claims 10, 12-14, 16-20, and 34-45 under 35 U.S.C. 103(a) as being unpatentable over Dumoutier *et al.* or U.S. Patent No. 6,551,799 in view of Llorente *et al.* is withdrawn. The current application has a priority date of April 28, 1999 which predates the publication or filing dates of all of the cited references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 12, 14, 16, 34-42, and 60-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating arthritis, does not reasonably provide enablement for methods of treating all autoimmune disorders. The

Art Unit: 1647

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention; 2) state of the prior art; 3) relative skill of those in the art; 4) level of predictability in the art; 5) existence of working examples; 6) breadth of claims; 7) amount of direction or guidance by the inventor; and 8) quantity of experimentation needed to make and/or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 10, 12, 14, 16, 34-42, and 60-61 are drawn to methods of treating autoimmune disorders. "Autoimmune disorders" encompasses rheumatoid arthritis, osteoarthritis, multiple sclerosis, myasthenia gravis, Crohn's disease, inflammatory bowel disease, lupus, diabetes, and psoriasis (claim 12). On p. 44 of the specification, Applicant states "an IL-22 inhibitor (such as an IL-22 antibody) can be used to treat an autoimmune disorder. Applicant goes on to list connective tissue disease, autoimmune pulmonary inflammation, Guillain-Barre syndrome, autoimmune thyroiditis, myasthenia gravis, graft-versus-host disease, and autoimmune inflammatory eye disease.

In Example 9, Applicant teaches that arthritic mice treated with an anti-IL-22 antibody showed significantly decreased symptoms relative to mice administered controls. The art is silent, however, to the involvement of IL-22 in other autoimmune disorders and whether administering anti-IL-22 antibodies would be useful in the treatment of any other autoimmune disorders. Interleukins have been implicated in a number of biological functions, and often it is not clear if they have beneficial or harmful effects. For instance, while it is known that IL-22 plays a role in inflammatory responses, and it may sometimes be beneficial to inhibit inflammatory responses, it has recently been shown that IL-22 plays a protective role in T cell-mediated hepatitis and it is a survival factor for hepatocytes (Radaeva *et al.* (2004), *Hepatology* 39(5): 1332-1342). Radaeva *et al.* teach that injection of concanavalin A (conA) and neutralizing IL-22 antibodies induced massive necrosis in the liver, whereas injection of conA alone led to spotted necrosis in the liver (p. 1335, column 1). Pretreatment with IL-22 almost completely prevented the massive necrosis of the liver. One of skill in the art would not know whether

Art Unit: 1647

inhibiting IL-22 would be successful in the treatment of any autoimmune disorder other than arthritis. Because of the lack of working examples, the breadth of the claims, and the lack of direction provided by Applicant, it would require undue experimentation by one of skill in the art to practice the invention as claimed without further guidance from the instant specification.

Conclusion

Claims 17-20, 43-59 and 62 are allowed.

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 17-20, 43-59, and 62 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
9/24/04


JANET ANDRES
PRIMARY EXAMINER